

immunochemical techniques, antibodies to *S. cerevisiae* (baker's or brewer's yeast) in human serum or plasma. Detection of *S. cerevisiae* antibodies may aid in the diagnosis of Crohn's disease.

(b) *Classification*. Class II (special controls). The special control is FDA's "Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications."

[65 FR 70307, Nov. 22, 2000]

§ 866.5800 Seminal fluid (sperm) immunological test system.

(a) *Identification*. A seminal fluid (sperm) immunological test system is a device that consists of the reagents used for legal purposes to identify and differentiate animal and human semen. The test results may be used as court evidence in alleged instances of rape and other sex-related crimes.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[54 FR 25047, June 12, 1989, as amended at 66 FR 38793, July 25, 2001]

§ 866.5820 Systemic lupus erythematosus immunological test system.

(a) *Identification*. A systemic lupus erythematosus (SLE) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and other body fluids that react with cellular nuclear double-stranded deoxyribonucleic acid (DNA) or other nuclear constituents that are specifically diagnostic of SLE. Measurement of nuclear double-stranded DNA antibodies aids in the diagnosis of SLE (a multisystem autoimmune disease in which tissues are attacked by the person's own antibodies).

(b) *Classification*. Class II (performance standards).

§ 866.5860 Total spinal fluid immunological test system.

(a) *Identification*. A total spinal fluid immunological test system is a device

that consists of the reagents used to measure by immunochemical techniques the total protein in cerebrospinal fluid. Measurement of spinal fluid proteins may aid in the diagnosis of multiple sclerosis and other diseases of the nervous system.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38793, July 25, 2001]

§ 866.5870 Thyroid autoantibody immunological test system.

(a) *Identification*. A thyroid autoantibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the thyroid autoantibodies (antibodies produced against the body's own tissues). Measurement of thyroid autoantibodies may aid in the diagnosis of certain thyroid disorders, such as Hashimoto's disease (chronic lymphocytic thyroiditis), nontoxic goiter (enlargement of thyroid gland), Grave's disease (enlargement of the thyroid gland with protrusion of the eyeballs), and cancer of the thyroid.

(b) *Classification*. Class II (performance standards).

§ 866.5880 Transferrin immunological test system.

(a) *Identification*. A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and other body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

(b) *Classification*. Class II (performance standards).

§ 866.5890 Inter-alpha trypsin inhibitor immunological test system.

(a) *Identification*. An inter-alpha trypsin inhibitor immunological test system is a device that consists of the

reagents used to measure by immunochemical techniques the inter-*alpha* trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter-*alpha* trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 53 FR 11253, Apr. 6, 1988; 65 FR 2313, Jan. 14, 2000]

Subpart G—Tumor Associated Antigen immunological Test Systems

§866.6010 Tumor-associated antigen immunological test system.

(a) *Identification*. A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

(b) *Classification*. Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled "Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s to FDA," and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.

[62 FR 66005, Dec. 17, 1997]

PART 868—ANESTHESIOLOGY DEVICES

Subpart A—General Provisions

Sec.

868.1 Scope.

868.3 Effective dates of requirement for premarket approval.

868.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

- 868.1030 Manual algesimeter.
- 868.1040 Powered algesimeter.
- 868.1075 Argon gas analyzer.
- 868.1100 Arterial blood sampling kit.
- 868.1120 Indwelling blood oxyhemoglobin concentration analyzer.
- 868.1150 Indwelling blood carbon dioxide partial pressure (P_{CO2}) analyzer.
- 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.
- 868.1200 Indwelling blood oxygen partial pressure (P_{O2}) analyzer.
- 868.1400 Carbon dioxide gas analyzer.
- 868.1430 Carbon monoxide gas analyzer.
- 868.1500 Enflurane gas analyzer.
- 868.1575 Gas collection vessel.
- 868.1620 Halothane gas analyzer.
- 868.1640 Helium gas analyzer.
- 868.1670 Neon gas analyzer.
- 868.1690 Nitrogen gas analyzer.
- 868.1700 Nitrous oxide gas analyzer.
- 868.1720 Oxygen gas analyzer.
- 868.1730 Oxygen uptake computer.
- 868.1750 Pressure plethysmograph.
- 868.1760 Volume plethysmograph.
- 868.1780 Inspiratory airway pressure meter.
- 868.1800 Rhinomanometer.
- 868.1840 Diagnostic spirometer.
- 868.1850 Monitoring spirometer.
- 868.1860 Peak-flow meter for spirometry.
- 868.1870 Gas volume calibrator.
- 868.1880 Pulmonary-function data calculator.
- 868.1890 Predictive pulmonary-function value calculator.
- 868.1900 Diagnostic pulmonary-function interpretation calculator.
- 868.1910 Esophageal stethoscope.
- 868.1920 Esophageal stethoscope with electrical conductors.
- 868.1930 Stethoscope head.
- 868.1965 Switching valve (ploss).
- 868.1975 Water vapor analyzer.

Subpart C—Monitoring Devices

- 868.2025 Ultrasonic air embolism monitor.
- 868.2300 Bourdon gauge flowmeter.
- 868.2320 Uncompensated thorpe tube flowmeter.
- 868.2340 Compensated thorpe tube flowmeter.
- 868.2350 Gas calibration flowmeter.
- 868.2375 Breathing frequency monitor.
- 868.2380 Nitric oxide analyzer.
- 868.2385 Nitrogen dioxide analyzer.
- 868.2450 Lung water monitor.
- 868.2480 Cutaneous carbon dioxide (P_cCO₂) monitor.
- 868.2500 Cutaneous oxygen monitor.
- 868.2550 Pneumotachometer.
- 868.2600 Airway pressure monitor.
- 868.2610 Gas pressure gauge.
- 868.2620 Gas pressure calibrator.
- 868.2700 Pressure regulator.